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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/887,593	06/21/2001	Daniel E. Afar	G&C 129.18USD1	9040

7590

08/21/2002

Attention of Karen S. Canady
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6701 Center Drive West, Suite 1050
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EXAMINER

NICKOL, GARY B

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 08/21/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/887,593

Applicant(s)

AFAR ET AL.

Examiner

Gary B. Nickol Ph.D.

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 16-71 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-5, 16-71 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claims 6-15 were cancelled.

Claims 1-5, 16-71 are pending.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-5, 16, 69-70 drawn to isolated BPC polypeptides and vaccine compositions thereof, classified in class 530, subclasses 300,350; class 514, subclass 2.
- II. Claims 17-28, 30, 34, 36-37, drawn to isolated antibodies and hybridomas, classified in class 530, subclasses 387.1+; class 435, subclass 326.
- III. Claim 29, drawn to a transgenic animal, classified in class 800, subclass 13.
- IV. Claims 31-33, drawn to a recombinant protein comprising the antigen binding region of a monoclonal antibody, classified in class 530, subclass 300/350.
- V. Claims 38-41, drawn to an assay for detecting BPC polypeptides in a biological sample, classified in class 435, subclass 7.23.

- VI. Claims 42-43, drawn to an assay for detecting BPC mRNA and polynucleotides, classified in class 435, subclass 6.
- VII. Claims 44-49, 53-55 drawn to a method of detecting cancer by quantifying the amount of BPC protein, classified in class 436, subclass 64; class 424, subclass 9.1.
- VIII. Claims 50-52, drawn to a method of detecting/diagnosing cancer by quantifying the amount of BPC mRNA, classified in class 436, subclass 64; class 424, subclass 9.1; class 435, subclass 6.
- IX. Claims 56-57, drawn to a method for treating cancer comprising administering an antibody, classified in class 424, subclasses 130.1.
- X. Claims 35, 58-59, drawn to a method for treating a patient with a cancer that expresses BPC-1 comprising administering a vector that expresses a single chain monoclonal antibody, classified in class 514, subclass 44.
- XI. Claims 60-65, drawn to a method of treating a patient with a cancer that expresses BPC comprising administering an antisense polynucleotide, classified in class 514, subclass 44.

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- XII. Claim 66,68 drawn to a method of treating a patient with a cancer that expresses BPC comprising inhibiting the processing of BPC in the cells of said cancer, classified in class 436, subclass 64.
- XIII. Claim 67, drawn to a method of treating a patient with a cancer that expresses BPC comprising inhibiting the secretion of BPC from the cells of said cancer, classified in class 436, subclass 64.
- XIV. Claim 71, drawn to a method of preventing a cancer expressing BPC comprising administering an immunogenic portion of a BPC polypeptide, classified in class 424, subclass 184.1.

The inventions are distinct, each from the other because of the following reasons:

The Inventions of Groups I-IV represent separate and distinct products which are made by materially different methods, and are used in materially different methods which have different modes of operation, different functions and different effects.

The inventions of Groups V-XIV are materially distinct methods which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success.

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The invention of Group I and the method of Group XIV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown:

(I) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § 806.05(h)]. In the instant case the polypeptide products as claimed can be used in a materially different process such as affinity chromatography.

The invention of Group II and the method of Groups V, VII, IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (I) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § 806.05(h)]. In the instant case the antibody products as claimed can be used in a materially different process such as affinity chromatography.

The invention of Group IV and the method of Groups V, VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (I) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § 806.05(h)]. In the instant case the polypeptide products as claimed can be used in a materially different process such as affinity chromatography.

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The invention of Group I-IV and the methods of Groups VI, VIII, and X-XIII are not at all related because the products of Groups I-IV are not used in any of the methods of Groups VI, VIII, and X-XIII.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Furthermore, because these inventions are distinct for the reasons given above and the search required for one group is not required for another group, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 703-305-7143. The examiner can normally be reached on M-F, 8:30-5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-4242 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Gary B. Nickol, Ph.D.
Examiner
Art Unit 1642

GBN
August 20, 2002

